DOCKET NO.: CELL-0276 PATENT

Applicati n No.: Not Yet Assigned

Preliminary Amendment - First Action Not Yet Received

This listing of claims will replace all prior versions, and listings, of claims in the application.

## **Listing of Claims:**

1. (currently amended) A composition for modulating the <u>an</u> immune response in a subject comprising a mutein of interleukin-1 (IL-1) having reduced toxicity to a human compared to the corresponding wild-type IL-1, provided that the mutein is not a mutein of precursor human interleukin-1β (IL-1β) in which the arginine at position 127 has been replaced with another amino acid, or the mutein is not a mutein of mature human IL-1β in which the arginine at position 11 has been replaced with another amino acid.

- 2. (original) The composition according to claim 1, wherein said IL-1 is IL-1\u00e18.
- 3. (original) The composition according to claim 1, wherein said IL-1 is mature IL-1β.
- 4. (original) The composition according to claim 1, wherein said IL-1 is human IL-1.
- 5. (original) The composition according to claim 1, wherein a positively charged residue of said IL-1 has been replaced with any of the other 17 natural amino acids.
- 6. (original) The composition according to claim 5, wherein said positively charged residue is arginine or lysine.
  - 7. (canceled)
- 8. (original) A method of modulating the immune response of a subject to a vaccine antigen comprising administering an effective amount of interleukin-1 (IL-1) mutein having reduced toxicity, in concurrent or sequential combination with said vaccine antigen.
  - 9. (original) The method according to claim 8, wherein said IL-1 is IL-1B.

DOCKET NO.: CELL-0276 PATENT

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Preliminary Amendment - First Action Not Yet Received

10. (original) The method according to claim 8, wherein said IL-1 is mature IL- $1\beta$ .

- 11. (original) The method according to claim 8, wherein said IL-1 is human IL- $1\beta$ .
- 12. (original) The method according to claim 8, wherein a positively charged residue of said IL-1 has been replaced with any of the other 17 natural amino acids.
- 13. (original) The method according to claim 12, wherein said positively charged residue is arginine or lysine.
- 14. (original) The method according to claim 13, wherein said IL-1 is mature human IL-1β and wherein said positively charged residue replaced is arginine at position 127.
- 15. (original) The method according to claim 8, wherein said vaccine antigen is selected from the group consisting of proteins, peptides, hormones and glycoproteins.
- 16. (original) The method according to claim 8, wherein said vaccine antigen is selected from the group consisting of viral antigen, fungal antigen, parasitic antigen, bacterial antigen, allergen, auto-immune related antigen and tumor-associated antigen.
- 17. (original) The method according to claim 8, wherein said IL-1 mutein is administered by a method selected from the group consisting of mucosally, intramuscularly and subcutaneously.
- 18. (original) The method according to claim 8, wherein said IL-1 mutein is administered in a pharmaceutically acceptable vehicle.
- 19. (original) The method according to claim 8, wherein said subject is a vertebrate.

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20. (original) The method according to claim 8, wherein said subject is human.